Citation:

Bazzano LA, He J, Ogden LG, Loria C, Vupputuri S, Myers L, Whelton PK. Legume consumption and risk of coronary heart disease in US men and women: NHANES I Epidemiologic Follow-up Study. *Arch Intern Med.* 2001 Nov 26; 161 (21): 2,573-2,578.

PubMed ID: 11718588

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the relationship between legume consumption and risk of coronary heart disease (CHD).

Inclusion Criteria:

Participants of the prospective cohort study of the NHANES I [Nutrition Examination Survey Epidemiologic Follow-up Study (NHEFS)]

Exclusion Criteria:

- Those who had a self-reported history of heart attack, heart failure or stroke at baseline
- Those who had used medication for heart disease in the prior six months
- NHANES I augmentation Survey participants that did not have a dietary assessment as part of the study protocol
- Those who lacked legume intake information.

Description of Study Protocol:

Recruitment

Subjects who participated in the NHEFS prospective cohort study.

Design

- Baseline data (1971-1975) from individuals ages 25-74 years at the time consisting of dietary assessment, medical examination, anthropometric measurements, medical history and laboratory tests were identified

- Blood pressure, body weight and height were obtained at baseline
- Data on physical activity, education, alcohol consumption were obtained at baseline
- Baseline information on smoking was obtained in a subset of 6,913 participants
- Follow-up data were collected between 1982 and 1984 and in 1986,1987 and 1992
- Follow-up examination included performing an in depth interview, obtaining hospital and nursing home records, and for decedents acquiring a death certificate.

Dietary Intake/Dietary Assessment Methodology

- Baseline dietary assessment included a three month food-frequency questionnaire (FFQ) on usual consumption of food groups in 13 categories including legumes
- In addition to the FFQ a 24-hour dietary recall collected by trained NHANES personnel was obtained
  - Portion sizes were also determined
- Legume intake was grouped into four categories: Intake less than once a week, once a week, two to three times a week and four or more times a week.

Statistical Analysis

- For each baseline characteristic the mean value or percentage of study participants was calculated by category of legume intake
- Significance in differences was examined by analysis of variance for continuous variables and χ^2 for categorical variables
- Cumulative incidence of CVD was calculated using the Kaplan-Meijer methods
- Cox proportional hazard models were used to explain the relationship between categories of legume intake and risk of CVD.

Data Collection Summary:

Timing of Measurements

- Baseline data 1971-1975
- History of CHD 1982,1984,1986,1987 and 1992.

Dependent Variables

Incidence of CVD and CHD obtained through medical records and death certificates.

Independent Variables

Number of servings per week of legumes.

Control Variables

- Baseline characteristics of:
  - Blood pressure
  - Total cholesterol (TC)
  - Diabetes
  - BMI
  - Physical activity
  - Education
  - Cigarette smoking

- Alcohol consumption
- Vitamin supplement use
- Intake of saturated fat
- Energy intake.

Description of Actual Data Sample:

- *Initial N:* 14,407
- *Attrition:* N=9,632 after exclusion criteria applied
- *Age:* 25-74 years at baseline
- *Ethnicity:*
- *Other relevant demographics:* For the baseline sample, low income, women of childbearing age and the elderly were over sampled
    - Individuals with higher intake of legumes
        - Tended to be younger and male
        - Less hypertension
        - Lower levels of cholesterol and hypercholesterolemia
        - Less diabetes
        - Lower BMI
        - Be more physically active
        - More likely to smoke
        - Less likely to have completed high school
        - Consume more saturated fat and have higher total energy intake
- *Anthropometrics:* BMI=Approximately 25±5kg/m^2
- *Location:* United States.

Summary of Results:

Over an average of 19 years of follow-up, 1,802 incident cases of CHD and 3,680 incident cases of CVD were documented.

Relative Risk of Coronary Heart Disease and Cardiovascular Disease According to Frequency of Legume Intake in 9,632 NHEFS Participants*					
Variable	**Less Than Once N=3,885**	**Once N=2,128**	**Two to Three Times N=2,226**	**At Least Four Times N=1,393**	**P-value for Trend**
	Coronary Heart Disease				
Number of events	812	355	401	234	
RR (95% CI)					
Multivariate model 1^	1.00	0.91 (0.79-1.04)	0.9 1(0.81-1.01)	0.78 (0.68-0.90)	0.002
Multivariate model 2 ^^	1.00	0.93 (0.81-1.07)	0.90 (0.81-1.01)	0.79 (0.69-0.91)	0.003

	Cardiovascular Disease				
Number of events	1,593	758	816	511	
RR (95% CI)					
Multivariate model 1^	1.00	0.96 (0.87-1.06)	0.94 (0.87-1.02)	0.89 (0.80-0.98)	0.02
Multivariate model 2^^	1.00	0.99 (0.90-1.08)	0.95 (0.88-1.03)	0.91 (0.82-1.01)	0.06

RR=relative risk, CI=confidence interval

^ Stratified by birth cohort and adjusted for age, sex, race, history of diabetes, recreational physical activity, level of education, regular alcohol consumption, current cigarette smoking and total energy intake N=9,178.

^^ Additionally adjusted for total serum cholesterol level, systolic blood pressure, BMI, saturated fat intake, frequency of meat and poultry intake, and frequency of fruit and vegetable intake; N=9,078

Other Findings

- When patients were stratified into age groups <60 years and at least 60 years, these associations were detected in the older age group but not the younger
- Those in older group with intake of beans four times or more per week had a 38% lower risk of CHD (RR=0.62; 95%CI: 0.50-0.77) and 27% lower risk of CVD (RR=0.73; 95%CI=0.62-0.87) compared to participants who consumed legumes less than once a week.\

Author Conclusion:

The authors conclude that their study showed a strong inverse relationship between legume intake and risk of CHD.

Reviewer Comments:

No other dietary assessment was done other than the baseline assessment in 1971-1975.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes